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10/553,426	01/24/2007	Hiroshi Yatsuhashi	042715-5016	1411

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
COLEMAN, CHARLES P.	
ART UNIT	PAPER NUMBER
3626	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,426	YATSUHASHI ET AL.	
	Examiner	Art Unit	
	CHARLES P. COLEMAN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-10 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

1. This action is in reply to the Amendment/Response filed on 11/12/2009.
2. Claims 5, 8-10 and 14-16 have been amended.
3. Claims 1-4 and 11-13 have been cancelled.
4. Claim 17 is new.
5. Claims 5-10 and 14-17 are currently pending and have been examined.
6. With the amendment of the Abstract, Applicant has successfully overcome the Examiner's objection to the Abstract and Examiner withdraws his objection to the Abstract.
7. With the cancellation of claims 1-4 and 11-13, and the amendment of claims 5, 8-10 and 14-16, applicant has successfully overcome the Examiner's 35 USC 101 rejection and Examiner withdraws his 35 USC 101 rejection.

Information Disclosure Statement

8. The Information Disclosure Statement filed on 8/18/2009 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 5-7, 9-10, 14 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Eils (US 2004/0076984 A1)

CLAIM 5

As per claim 1, Eils teach a disease prognosis prediction device for the prognosis of the disease from clinical laboratory test values comprising:

- a computer having a memory that stores a judgment routine (Eils, [0001] and [0002], page 1);
- an input means that inputs a name of the disease which is an object of the prognosis prediction and clinical laboratory test measurement values for the disease (Eils, [0001] and [0002], page 1);
- a prognosis prediction value acquisition means that determines the prognosis prediction value for the disease by applying the input values to the judgment routine (Eils, [0001] and [0002], page 1);
- and a display processing means that displays the prognosis prediction value (Eils, [0001] and [0002], page 1),
- wherein said judgment routine is obtained by a method for preparing a model for predicting the prognosis of a specified disease from clinical laboratory test values for the disease (Eils, [0001] and [0002], page 1) which comprises the steps of:
- inputting a plurality of actually measured clinical laboratory test values for the disease and actual measured values of the prognoses into the computer (Eils, [0001] and [0002], page 1);
- processing these values by a data mining method to determine one or a plurality of clinical laboratory test items which have an influence on the prognosis of the disease (Eils, [0001] and [0002], page 1);
- determining a priority of the items with respect to the prognosis in a case where there are a plurality of the items (Eils, [0001] and [0002], page 1);
- and establishing a judgment routine in which correlation of the plurality of clinical laboratory test items and the clinical laboratory test value ranges of the test items with the predicted value of the prognosis is stipulated on the basis of the priority (Eils, [0001] and [0002], page 1).

CLAIM 6

As per claim 6, Eils teaches the device of claim 5 and further discloses the limitations of:

- a computer program which causes a computer to execute the respective means according to claim 5, and which is readable by a computer (Eils, [0001] and [0002], page 1).

CLAIM 7

As per claim 7, Eils teaches the device of claim 6 and further discloses the limitations of:

- a storage medicum in which the program according to claim 6 is stored (Eils, [0001] and [0002], page 1).

CLAIM 9

As per claim 9, Eils teaches the device of claim 5 and further discloses the limitations of:

- wherein the judgment routine is a decision tree in which a plurality of chance nodes are taken as the clinical laboratory test items and clinical laboratory test measurement value ranges, and a plurality of prognosis prediction values corresponding to the chance nodes are taken as terminal nodes (Eils, [0001] and [0002], page 1).

CLAIM 10

As per claim 10, Eils teach the device of claim 5 and further discloses the limitations of:

- wherein the chance nodes of the decision tree comprises patient information (Eils, [0001] and [0002], page 1).

CLAIM 14

As per claim 14, Eils teaches the device of claim 5 and further discloses:

- wherein the priority of the clinical test items is determined each time in the process of the judgment routine (Eils, [0001] and [0002], page 1).

CLAIM 17

As per claim 17, Eils teach the device of claim 5 and further discloses the limitations of:

- wherein the judgment routine is a decision tree in which a plurality of chance nodes are taken as the clinical laboratory test items and the clinical laboratory test measurement value ranges, and a plurality of prognosis prediction values corresponding to the chance nodes are taken as terminal nodes (Eils, [0001] and [0002], page 1).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 8 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eils (US 2004/0076984 A1), in view of Watanabe et al. (US 5,516,640), as applied to claims 1-7, 9-12 and 14 above.

CLAIM 8

As per claim 8, Eils teach the device of claim 5.

Eils does not teach:

- wherein the disease comprises a liver disease, and the clinical laboratory test item with the highest priority comprises PIVKA.

Watanabe et al. teach:

- wherein the disease comprises a liver disease, and the clinical laboratory test item with the highest priority comprises PIVKA (Watanabe et al., column 1, lines 47-49).

It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the system of Eils to include compatibility with the Health Level 7 transaction data format as recited above. One of ordinary skill in the art at the time of the invention would have been motivated to expand the system of

Eils in **because PIVKAs are produced in the blood as a result of hepatocellular carcinoma** (Watanabe et al., column1, lines 47-49).

CLAIM 15

As per claim 15, Eils teach the device of claim 5.

Eils does not teach:

- wherein the disease relates to a liver disease, and the highest chance node is set at a critical value relating to the clinical test value of PIVKA.

Watanabe et al. teach:

- wherein the disease relates to a liver disease, and the highest chance node is set at a critical value relating to the clinical test value of PIVKA (Watanabe et al., column1, lines 47-49).

The motivation for making this modification to the teachings of Eils is the same as that set forth above in the rejection of claim 8.

CLAIM 16

As per claim 16, Eils teach the device of claim 5.

Eils does not teach:

- wherein PIVKA reference value is set for each year of survival years when survival predictions in which PIVKA is the node with the highest priority are performed on the basis of the model for each year of survival years.

Watanabe et al. teach:

- wherein PIVKA reference value is set for each year of survival years when survival predictions in which PIVKA is the node with the highest priority are performed on the basis of the model for each year of survival years (Watanabe et al., column1, lines 47-49).

The motivation for making this modification to the teachings of Eils is the same as that set forth above in the rejection of claim 8.

Response to Arguments

14. Applicant's arguments filed 11/12/2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 11/12/2009.

15. Applicant argues that Eils does not anticipate the present invention because (A) Eils does not disclose or suggest the determination of a priority of clinical test items for the prognosis of a disease where there are a plurality of test items, (B) Eils fails to disclose or suggest the establishment of a judgment routine in which correlation of the plurality of clinical laboratory test items and the clinical laboratory test value ranges of the test items with the predicted value of the prognosis is stipulated on the basis of the priority.

16. With respect to both arguments (A) and (B), Examiner respectfully disagrees with Applicant's arguments that (A) Eils does not disclose or suggest the determination of a priority of clinical test items for the prognosis of a disease where there are a plurality of test items, (B) Eils fails to disclose or suggest the establishment of a judgment routine in which correlation of the plurality of clinical laboratory test items and the clinical laboratory test value ranges of the test items with the predicted value of the prognosis is stipulated on the basis of the priority. Eils discloses and suggests of the use of at least Artificial Neural Networks (ANN), Bayesian Belief Networks (BBN) and several different clustering approaches for classification or prediction of diseases using many types clinical data (Eils, [0001]-[0018]). Inherent in the use of and in the definition of ANN, BBN and clustering technologies and techniques is the ability to determine a priority of clinical test items for the prognosis of a disease where there are a plurality of test items. Further, each of these techniques (ANN, BBN, clustering) provides for the establishment of a judgment routine in which correlation of the plurality of clinical laboratory test items and the clinical laboratory test value ranges of the test items with the predicted value of the prognosis is stipulated on the basis of the priority. Applicant's argument is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set for in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension free pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHARLES P. COLEMAN whose telephone number is 571-270-7788. The examiner can normally be reached on Monday through Thursday 7:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GERALD (JERRY) O'CONNOR can be reached on 571-272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. P. C./
Examiner, Art Unit 3626

/Robert Morgan/
Primary Examiner, Art Unit 3626